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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,954	07/08/1999	NICHOLAS KIM HAYWARD	10441Z	7397

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
1647	18

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/349,954</b>	Applicant(s) <b>HAYWARD et al.</b>	
	Examiner <b>Christine Saoud</b>	Art Unit <b>1647</b>	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
<b>Period for Reply</b>			
<p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p>			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
<p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Oct 5, 2001</u></p>			
<p>2a) <input type="checkbox"/> This action is <b>FINAL</b>.</p>		<p>2b) <input checked="" type="checkbox"/> This action is non-final.</p>	
<p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>			
<b>Disposition of Claims</b>			
<p>4) <input checked="" type="checkbox"/> Claim(s) <u>26-28, 30, and 46-58</u> is/are pending in the application.</p>			
<p>4a) Of the above, claim(s) _____ is/are withdrawn from consideration.</p>			
<p>5) <input checked="" type="checkbox"/> Claim(s) <u>26-28, 30, 47, and 56-58</u> is/are allowed.</p>			
<p>6) <input checked="" type="checkbox"/> Claim(s) <u>46 and 48-55</u> is/are rejected.</p>			
<p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p>			
<p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>			
<b>Application Papers</b>			
<p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p>			
<p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.</p>			
<p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved.</p>			
<p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>			
<b>Priority under 35 U.S.C. § 119</b>			
<p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).</p>			
<p>a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p>			
<p>1. <input type="checkbox"/> Certified copies of the priority documents have been received.</p>			
<p>2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</p>			
<p>3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p>			
<p>*See the attached detailed Office action for a list of the certified copies not received.</p>			
<p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).</p>			
<b>Attachment(s)</b>			
<p>15) <input type="checkbox"/> Notice of References Cited (PTO-892)</p>		<p>18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p>	
<p>16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p>		<p>19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p>	
<p>17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____</p>		<p>20) <input type="checkbox"/> Other: _____</p>	

## DETAILED ACTION

### *Response to Amendment*

1. Claims 43-45 have been canceled and claims 46-58 have been added as requested in the amendment of paper #17, filed 05 October 2001. Claims 26-28, 30 and 46-58 are pending in the instant application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed 05 October 2001 have been fully considered but they are not deemed to be persuasive.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 50-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 50-55 are directed to a process of making a biologically active polypeptide by expressing a nucleic acid molecule which hybridizes to a coding nucleic acid molecule. However, that nucleic acid molecule which hybridizes would be the complementary strand, which is not coding. Therefore, it would not encode a polypeptide, and the instant specification is not enabled for making a biologically active polypeptide with the complementary nucleic acid molecule, absent evidence to the contrary.

7. Claims 50-55 are also not enabled for making a “biologically active VEGF-B” by using a nucleic acid molecule with hybridizes under high stringency conditions. These claims are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making biologically active VEGF-B by expressing a nucleic acid molecule of SEQ ID NO:3, 5, 7 or 9, does not reasonably provide enablement for expressing a nucleic acid molecule which hybridizes under high stringency conditions to said nucleic acid molecules of SEQ ID NO:3, 5, 7 or 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are broader than the enabling disclosure in that the instant specification teaches specific nucleic acid molecules which encode a biologically active VEGF-B molecule. However, the instant claims are not enabled for this breadth because it is not predictable which of those nucleic acid molecules which hybridize to the nucleic acid sequences of SEQ ID NO:3, 5, 7 or 9 will encode a biologically active VEGF-B. It would require undue experimentation to

practice the current invention because one of ordinary skill in the art would not know which of those nucleic acid molecules that hybridize would also encode a polypeptide, which could be considered “VEGF-B” until the polynucleotide is expressed in a host cell, the protein produced and tested. Therefore, the instant claims are a wish to know, and do not meet the requirements of enablement. Furthermore, the claims fail to recite sufficient structural elements to provide for the necessary function in that the structure of hybridizing to the sequence of SEQ ID NO:3, 5, 7 or 9 is not sufficient for encoding a biologically active VEGF-B, therefore, the claims are not enabled. See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. Apps, and Interf. 1986) and *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

The instant fact pattern is directly analogous in that what is claimed are nucleic acid molecules that have yet to be isolated or characterized for the activity recited in the application and thereby constitutes a “wish to know” rather than a reduction to practice, absent evidence to the contrary. The decisions of *In re Fisher*, Amgen Inc. v. Chugai, and *In re Wands* are relied upon in the instant rejection (see below) and by the court in a recent CAFC decision, Genentech, Inc. V. Novo Nordisk, 42 USPQ2d, 100 (CAFC 1997) because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of the claims must be based upon the predictability of the claimed subject matter and no on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner

disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not without actually making and testing them, then the instant application does not support the breadth of the claims.

The issue is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This position is consistent with the decisions in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) and Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd., 13 USPQ2d, 1737 (1990) and In re Wands, 8 USPQ2d, 1400 (CAFC 1988). The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims.

Due to the large quantity of experimentation necessary to generate the large number of molecules by the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art, and the breadth of the claims, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive

contribution on the part of a practitioner which would involve the determination of which of those molecules which meet the structural limitations of the claims would also meet the functional limitations of the claims. It is this additional characterization and inventive contribution that is required in order to obtain the functional and structural data needed to permit one to practice the claimed invention that constitutes undue experimentation.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 46, 48 and 49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 47, 45 and 46, respectively, of copending Application No. 08/765,588. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to methods of making polypeptides using specific nucleic acid molecules, and the claims of '588 are directed to nucleic acid molecules encoding the polypeptides. Such method claims of '588 were not

restricted from the nucleic acid claims and it is *prima facie* obvious to use the nucleic acid which encodes the polypeptide in a method of making the polypeptide. The methods of the instant application encompass using nucleic acids encompassed by the claims of '588, therefore, the subject matter clearly overlaps and is not patentably distinct, absent evidence to the contrary.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Allowable Subject Matter***

10. Claims 26-28, 30, 47, 56-58 are allowable over the prior art of record.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 19, 2001

CHRISTINE J. SAoud  
PRIMARY EXAMINER  
*Christine J. Saoud*